their measure relative to the diagnosis of CDAD is immaterial.

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DOI:10.1503/cmaj.1050257

## Canadian Healing Oil

I was interested in the photo of Canadian Healing Oil and the accompanying caption in a recent edition of The Left Atrium.[1] I grew up in the Caribbean and can attest to the fact that Canadian Healing Oil was an essential component of the home medicine cabinet. It was administered to me for all of the indications described on the bottle label. I had to take it orally and via steam inhalation; it was also used as ear drops to remove wax and relieve earaches. I had assumed that the product included some kind of oil from Canadian pine trees, but it appears that the only uniquely Canadian ingredient is sulphonated seal oil.

Canadian Healing Oil was a soothing balm for us in the Caribbean; perhaps its effect is comparable to the soothing effect of Caribbean rum on the Canadian psyche. Both products must be used prudently, of course.

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DOI:10.1503/cmaj.1050233

## Is this clinical trial fully registered?

In September 2004, the International Committee of Medical Journal Editors (ICMJE) proposed a specific registration for clinical trials whose authors expect consideration for publication.[1] Registration of clinical trials is an important issue. However, we felt uncomfortable with this proposal. Indeed, the ICMJE definition of clinical trial was quite ambiguous and ICMJE criteria excluded already mandatory registrations (i.e., European Medicines Agency).[2] Now, registration of any clinical trial to be submitted for publication is mandatory, and the ICMJE states "each journal editor will decide on a case-by-case basis about reviewing unregistered trials."[3] This new rule for manuscript evaluation lacks transparency, transparency which was an end of this registration proposal. Last, no evaluation of this policy is planned.

The key to improving knowledge and the quality of trials is not to inflate regulations and guidelines, but rather to enforce already existing ones. For example, editors should endorse and implement the CONSORT (Consolidated Standards of Reporting Trials) statement, which gives recommendations for reporting randomized controlled trials. Only 22% of high-impact medical journals refer to CONSORT in their advice to authors, but many use ambiguous language regarding what is expected or fail to cite the up-to-date version.[4] Please, no more clerical burden for the clinical investigator!

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**Competing interests:** None declared.

DOI:10.1503/cmaj.1060012

### [The Editor in Chief responds:]

Alain Braillon and Gérard Dubois ask some important questions.

The ICMJE definition of a clinical trial could not take into account the (multiple) definitions of clinical trials used by various registries. We were interested in capturing clinical trials that were likely to contain information relevant to clinical practice. The problem of definition is most acute for very early clinical trials, often referred to as Phase 2 trials, whose purpose can be to determine recruitment strategies, compliance, frequencies of primary outcomes and the like. These trials are not intended to provide meaningful outcomes that can be used to guide clinical or preventive practice. Although other national registries, such as the European Medicines Agency, may require these types of trials to be registered, the ICMJE does not. Obviously, the ICMJE is supportive of more inclusive registries.

Case-by-case consideration was added for several reasons, but chief among them was the vagueness of the definition of an eligible Phase 2 trial. We recognized that some Phase 2 trials, designed to help plan Phase 3 trials (and thus not in need of registration according to the ICMJE definition) might yield unanticipated information and results that had clinical applicability, such as an unexpected efficacious result or serious adverse events. Also, there was bound to be some failure to register, possibly among trialists from small centres or parts of the world that are not aware of the deadlines. We are reasonable bunch, and we are trying to be transparent.

We welcome efforts to evaluate the policy and expect that journalogists and others will be looking for results and tracking progress. We very much encourage groups such as yours to undertake this type of study.

Lastly, I agree that editors should do better at encouraging authors of accepted papers to use the CONSORT guidelines.

**John Hoey**
Editor in Chief
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**Competing interests:** I am a coauthor of the ICMJE statement on clinical trials registration and editor of a journal that supports efforts to publicly register clinical trials.

DOI:10.1503/cmaj.1060012